

	Typ e	L #	Hits	Search Text	DBs	Time Stamp	Comm ents
1	BRS	L1	30	increment\$ same balloon same expansion and stent and catheter	USP AT; US- PGP UB; DER WEN T	2003/12/ 17 17:40	
2	BRS	L2	4	increment\$ adj6 balloon same expansion and stent and catheter	USP AT; US- PGP UB; DER WEN T	2003/12/ 17 17:41	
3	BRS	L3	1	increment\$ adj6 balloon same expansion and stent and catheter and (sheath or cover)	USP AT; US- PGP UB; DER WEN T	2003/12/ 17 17:42	
4	BRS	L4	2	increment\$ adj9 balloon same expansion and stent and catheter and (sheath or cover)	USP AT; US- PGP UB; DER WEN T	2003/12/ 17 17:43	

	Error Definition	Er ro rs
1		0
2		0
3		0
4		0

	Typ e	L #	Hits	Search Text	DBs	Time Stamp	Comm ents
5	BRS	L5	75	catheter same sheath same (slow\$ or increment\$) and balloon and stent	USP AT; US- PGP UB; DER WEN T	2003/12/ 17 17:53	
6	BRS	L6	6	5868755.URPN.	USP AT	2003/12/ 17 17:47	
7	BRS	L7	4	catheter same sheath same increment and balloon and stent	USP AT; US- PGP UB; DER WEN T	2003/12/ 17 17:54	
8	BRS	L8	15	catheter same sheath same increment\$ and balloon and stent	USP AT; US- PGP UB; DER WEN T	2003/12/ 17 17:54	

sposed on the catheter in the contracted condition.

Brief Summary Text - BSTX (8):

Embodiments may include one or more of the following features. The balloon is only initially radially constrained. The constraint is an axially slidable sheath which surrounds and partially constrains the balloon from inflation.

The sheath is designed to axially slide along a length of the balloon in response to a pressure in the balloon, such that the balloon may be

progressively incrementally inflated. The slidable sheath is adapted to slide

axially onto a shaft of the catheter so that the sheath may be retrieved from

the patient. The constraint is an elastomeric band which surrounds and

partially constrains the balloon from inflation. The elastomeric band is

disposed over a significant length of the balloon. The elasticity of the

elastomeric band varies, e.g., by varying the thickness of the band, from one

end of the balloon to the other to allow progressive incremental inflation of

the balloon. The elastomeric band has uniform elasticity over the portion of

the balloon on which it is disposed. The elastomeric band is disposed only

over a center region of the balloon and divides the balloon into a proximal and

a distal region. The tubular prosthesis is a stent. The balloon is

substantially nondistendible. The constraint is an axially slidable sheath

which surrounds the balloon, the sheath being formed of a low coefficient of

friction polymer. The polymer is teflon. The balloon has an inflatable

portion corresponding to the length of the prosthesis and the balloon and

prosthesis have a length of about 5 cm or more. The balloon and prosthesis

have a length in the range of about 8-12 cm. The

DOCUMENT-IDENTIFIER: US 20030144671 A1

TITLE: Delivery mechanism for implantable
stents-grafts

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Abstract Paragraph - ABTX (1):

A delivery mechanism for an implantable stent which provides a high mechanical advantage to the surgeon and convenient operation so as to facilitate smooth withdrawal of an outer catheter sheath following placement of the stent in the desired location within the patient's vessel. Preferred embodiments include a moving rail actuated by a V-shaped lever, a hydraulic actuator, a rack and pinion drive, and a power screw system. The delivery mechanism has a movable member that is attached to the outer catheter sheath so that actuating the mechanism results in an incremental movement of the moveable member, which in turn results in an incremental movement of the outer catheter sheath. Once the outer catheter sheath is retracted from the stent, the stent is deployed into the patient's vessel and the remaining parts of the mechanism, including an inner tube, an atraumatic tip, and a stabilizing element, are easily removed.

Title - TTL (1):

Delivery mechanism for implantable stents-grafts

Summary of Invention Paragraph - BSTX (2):

[0002] The present invention relates to implantable medical devices. More particularly, the present invention relates to mechanisms

for implanting a self-expanding stent graft which is used to sustain a weakened body vessel.

Summary of Invention Paragraph - BSTX (5):

[0004] A commonly used implant is a tubular-shaped wire frame known as a stent graft. In one type of stent graft, the wire frame is made of self-expanding nickel-titanium (nitinol) shape memory alloy which is laser cut and encapsulated within two layers of expanded polytetrafluoroethylene (ePTFE). The layers of ePTFE are processed such that the material forms a monolithic structure, fully enclosing the metallic stent where the cover is present. The encapsulation is intended to prevent restenosis of the vessel. The inner blood contacting lumen of the stent graft is impregnated with carbon. Typically, one or both ends of the stent graft is flared and free of encapsulation in order to facilitate anchoring within the vessel. The nitinol alloy is placed into the body during surgery at room temperature. As it increases to body temperature, it expands to its desired size. Balloon angioplasty may be done after implantation of the stent to set its final shape.

Summary of Invention Paragraph - BSTX (6):

[0005] In order to introduce the stent into the body vessel, it is placed within a tubular sheath catheter. When the device is positioned at the desired location, it is released from the tubular sheath and permitted to expand radially against the wall of the vessel. When the outer sheath is removed, the physician must be careful to avoid migration of the stent away from the desired location. Typical prior art devices employ a simple ratchet mechanism in conjunction with the outer sheath and an inner lumen. The

inner lumen is maintained stationary to fix the stent in position and the outer lumen is drawn away from the stent by means of the ratchet mechanism actuated by a spring loaded trigger. Each pull on the trigger causes the outer sheath to retract by an amount corresponding to the stroke of the trigger. An anchor to which the outer sheath is attached includes a tooth which engages with each tooth of the ratchet mechanism. This mechanism has drawbacks in that it is awkward to operate and difficult to maintain steady so that the stent graft does not migrate away from its desired position during sheath retraction.

Summary of Invention Paragraph - BSTX (8):

[0006] The present invention is directed to a stent delivery mechanism which is both easy to operate and facilitates extremely precise stent positioning.

Several different configurations are described. For example, in a first embodiment, a simple V-shaped grip aligned generally longitudinally with the catheter to be deployed is utilized. A mechanical advantage gear mechanism is employed, which operates in conjunction with a ratchet to smoothly retract a sheath hub to which the outer sheath of the catheter is attached. The mechanism is easy to grasp and actuate in any rotational configuration. The V-shaped mechanism includes a body which contains the ratchet and a drive gear lever handle. The lever handle interacts with a drive pinion to drive the ratchet by a predetermined amount, thus retracting the sheath hub by a corresponding amount. The drive gear lever handle mechanism provides both the mechanical advantage, which results in movement of the outer sheath by a relatively small amount for a large displacement of the lever handle, and a

much smoother operation than the direct ratchet operation of the prior art device.

Summary of Invention Paragraph - BSTX (12):

[0010] In order to further facilitate the stent deployment, the inner lumen of the delivery system may be formed of a metal spring, which is contained in its fully compressed state. The use of such a spring for the inner lumen provides significant advantages in that it is extremely flexible, enabling introduction of the catheter into the body and proper positioning of the stent, and yet is very rigid and non-compressible so as to maintain the stent in the desired position during outer sheath retraction.

Brief Description of Drawings Paragraph - DRTX (2):

[0012] FIG. 1 is a cross-sectional view of the end of a catheter illustrating a stent to be implanted;

Brief Description of Drawings Paragraph - DRTX (3):

[0013] FIG. 2 is a cross-sectional view of a first embodiment of the stent delivery mechanism of the present invention incorporating a moving rail mechanism;

Brief Description of Drawings Paragraph - DRTX (5):

[0015] FIG. 7 is an exploded view of a preferred embodiment of the stent delivery mechanism shown in FIG. 2.

Brief Description of Drawings Paragraph - DRTX (6):

[0016] FIG. 8 is a cross-sectional view of a second embodiment of the stent delivery mechanism of the present invention incorporating a hydraulic mechanism

Brief Description of Drawings Paragraph - DRTX (8):

[0018] FIG. 13 is a cross-sectional view of a third embodiment of the stent delivery mechanism of the present invention employing a rack and pinion thumb actuated drive system;

Brief Description of Drawings Paragraph - DRTX (11):

[0021] FIG. 17 is a cross-sectional view of a fourth embodiment of the stent delivery mechanism of the present invention employing a power screw drive system;

Detail Description Paragraph - DETX (4):

[0026] FIG. 1 illustrates the distal end of a catheter 11 having a stent 16 carried within it for implantation into the body of a patient. The proximal end of the catheter 11 is connected to any of the delivery mechanisms to be described, and the catheter 11 is of sufficient length to reach the point of implantation of the stent 16 from the introduction point into the body. The catheter 11 includes an outer sheath 10, a middle tube 12 which in the preferred embodiment is formed of a compressed spring, and a flexible (e.g., polyamide) inner tube 14. The outer sheath 10 preferably has an ePTFE liner with a polyether blocked amide plastic (pebax) basecoat with reinforced braid, and an external layer of pebax. A stent 16 for implantation into a patient is carried within the outer sheath 10. The stent 16 includes a nitinol memory metal alloy frame 18 which is formed in a criss-cross pattern which may be laser cut. Most or all of the length of the stent is encapsulated within two layers of ePTFE to form a monolithic body structure 20, fully enclosing the metallic stent 16 both internally and externally where the cover 20 is present.

One or both ends of the stent 16 may be left uncovered as illustrated at 22 and 24 to provide anchoring within the vessel where the stent 16 is to be implanted.

Detail Description Paragraph - DETX (6):

[0028] A generally cup-shaped element 28 is provided within the catheter 11 adjacent the rear end of the stent 16 and is attached to the end of the spring 12 by appropriate means, e.g., the cup element 28 may be plastic wherein the spring 12 is molded into its base, or the cup element 28 may be stainless steel wherein the spring 12 is secured by welding or the like. The open end of the cup element 28 serves to compress the end 24 of the stent 16 in order to provide a secure interface between the stent 16 and the spring 12. Alternatively, instead of a cup shape, the element 28 could be formed of a simple disk having either a flat or slightly concave surface for contacting the end 24 of the stent 16.

Detail Description Paragraph - DETX (7):

[0029] In order to deploy the stent 16 inside a body vessel during a surgical procedure, the catheter 11 is introduced into the designated vessel via an introducer positioned at the skin of the patient. As mentioned above, a guide wire may have previously been introduced into the vessel, in which case the catheter 11 is introduced by passing the tip 26 over the end of the guide wire outside of the patient and moving the catheter 11 along the path within the vessel which has been established by the guide wire.

Detail Description Paragraph - DETX (8):

[0030] The position of the catheter 11 is tracked by monitoring the tip 26

by means of a fluoroscope. When the catheter 11 is at the desired location i.e., when the stent 16 is positioned at the location where it is to be implanted, the movement of the catheter 11 is halted. The catheter 11 must then be removed, leaving the stent 16 in place at the desired location within the vessel. This is accomplished by initially retracting the outer sheath 10, i.e., towards the left in FIG. 1, until it no longer covers the stent 16. The spring 12 is maintained in a fixed position and, in conjunction with the cup element 28, serves to maintain the stent 16 in its desired position during the retraction of the outer sheath 10. After the outer sheath 10 has been retracted such that it no longer covers the stent 16 and the stent 16 is expanded, the tip 26 can be pulled back through the stent 16 until the tip 26 abuts the outer sheath 10. As illustrated, the diameter of the tip 26 is slightly greater than the inner diameter of stent 16 when it is inside the outer sheath 10. The stent 16 will expand as it heats up to body temperature as a result of its memory metal characteristics. The tip 26 is then pulled through the center of the stent 16 after the stent 16 has expanded following withdrawal of the sheath 10. Once the tip 26 has been pulled back against the outer sheath 10, the catheter 11 can be removed from the vessel of the patient. This retraction procedure ensures that the tip 26 does not get caught on or embedded in any body vessel when being pulled out of the patient.

Detail Description Paragraph - DETX (9):

[0031] As discussed above, the tube spring 12 is maintained stationary during the withdrawal of the outer sheath 10 and serves to keep the stent 16 in

its desired location. The tube spring 12 is very well suited for this task since it has extremely low compression in a longitudinal direction once it is fully compressed. It is also well suited for the introduction of the catheter 11 into the body vessel, since it is extremely flexible. Alternatively, other materials, such as various plastics materials, could be employed as the middle tube 12, so long as the compression is low to maintain stent positioning and the necessary flexibility is provided for moving through the vessel. In order to properly deploy the stent 16, the outer sheath 10 must be smoothly retracted while the tube spring 12 maintains its position. The present invention provides a number of mechanisms intended to perform this operation with maximum ease of use and minimal stent migration.

Detail Description Paragraph - DETX (10):

[0032] FIG. 2 illustrates a first embodiment of a delivery mechanism for implanting the stent 16. This mechanism is generally in the form of a V-shaped lever device having a housing shell 30 from which the outer sheath 10 extends. The sheath 10 is secured to a pawl/sheath hub 32. A spring pawl 34 attached to the hub 32 engages a ratchet 36 which is integrated into the housing shell 30. Movement of the sheath hub 32 within the housing shell 30 is thus constrained to moving to the right as shown in FIG. 2. The tube spring 12 is secured in a fixed position to a guide wire port 38. The interior of the device may be flushed by means of a flush stop cock 40. A ratchet rail 42 is provided at the bottom of the housing shell 30 and is reciprocal back and forth within the shell 30. The rail 42 includes ratchet teeth 44 on the upper side which engage with the spring pawl 34 and a rack gear 46 on the bottom surface thereof which

engages a pinion 48. The pinion 48 is rotated by means of a lever handle 50 which includes a drive gear 52. The lever handle 50 is spring biased by means of a spring 54 to its open position. Other types of springs, such as a spring contained within the pivot point 56 of the lever handle could alternatively be employed.

Detail Description Paragraph - DETX (12):

[0034] The described device is intended for use with stents of approximately 40-100 mm in length. In order to fully retract the outer sheath 10, the lever handle 50 must be closed and opened a number of times. FIG. 6 illustrates the mechanism in which the handle 50 has been operated to move the hub 32, and therefore the outer sheath 10, back to its completely rightmost position. In this position (or sooner depending upon the length of the stent) the outer sheath 10 will be completely away from the stent 16, allowing the stent 16 to expand. As described above, once the stent 16 expands, the inner tube 14 and tip 26 are pulled back through the middle of the stent 16 until the tip 26 is tight against the outer sheath 10. The entire catheter 11 can then be removed, leaving the stent 16 in place at the desired location.

Detail Description Paragraph - DETX (13):

[0035] A preferred embodiment of the device shown in FIG. 2 is illustrated by the exploded view in FIG. 7. In this view, a left housing assembly 31 and a right housing assembly 33 can be seen. An inner catheter assembly 37 is disposed between the housing assemblies 31 and 33 to support the tube spring 12 as well as the spring pawl 34. A strain relief member 51 fits over the end of housing shell 30 to reduce any potential pressure caused in the actuation of

the mechanism. A safety pin 53 is insertable into the lever handle 50 for additional protection. Upon completion of the deployment of the stent 16 and the retraction of outer sheath 10, a retractor sleeve 49 is pulled back slightly, releasing a retractor latch 47 from its locked position on the inner catheter assembly 37. The inner catheter assembly 37, which is coupled to the inner tube 14, is pulled back away from the housing assemblies 31 and 33 in order to retract the inner tube 14 far enough so that tip 26 is snugly against the outer sheath 10. The catheter 11, including the outer sheath 10, the inner tube 14 and the tip 26 can then be removed from the body. Retraction of the catheter 11 in this manner ensures that the tip 26 can not get caught on anything outside of the body or inside the delivery mechanism.

Detail Description Paragraph - DETX (14):

[0036] The gear mechanism including the lever gear 52, pinion 48 and rack 46 is designed to provide a mechanical advantage of approximately 4:1. The mechanical advantage along with the rotating pinion configuration provides very smooth and linear operation with minimal fly back during the return stroke. In addition, the lever handle configuration is extremely convenient, as it can be easily operated in almost any rotational orientation. This is important due to the fact that when a catheter is introduced into the patient, it is often necessary to rotate the catheter in order for it to most easily follow the desired path through the vessel to the stent location. Therefore, the final orientation when the stent is to be deployed is variable. The configuration of the V-shaped lever handle mechanism enables a simple gripping action to be applied, and is easily gripped by the surgeon regardless of

its final orientation. Generally, approximately ten cycles (i.e., squeezing and releasing) of the lever handle 50 are necessary to fully remove the outer sheath 10 from the stent. The configuration of this embodiment enables retraction to be done in a very smooth and linear fashion.

Detail Description Paragraph - DETX (15):

[0037] A second embodiment of the stent delivery mechanism is illustrated in FIG. 8. This delivery mechanism employs a hydraulic system to achieve extremely smooth operation. A housing 62 defines a reservoir chamber 64 within which is carried a piston 66. The outer sheath 10 is connected to the piston 66 to be moved therewith. A V-cup seal 68 prevents leakage of the hydraulic fluid carried within the housing. A piston displacement chamber 70 is defined between the piston 66 and the opening through which the sheath 10 exits.

Detail Description Paragraph - DETX (18):

[0040] Referring to FIG. 11, the plunger 80 is pressed inward to open the valve 78 and move fluid through the conduit 74 into the piston chamber 70, thus moving the piston 66 to the right by a fixed amount and, in turn, retracting the outer sheath 10 from the stent. In the present embodiment, one stroke of the plunger 80 provides approximately 1 cm of travel of the piston 66. The plunger and piston are sized to provide a mechanical advantage of approximately 4:1. By repeatedly operating the plunger, the piston 66 will be drawn back to its fully deployed position as illustrated in FIG. 12. At this point, the outer sheath 10 is fully withdrawn from the stent 16, and the catheter 11 can be pulled out of the patient as described above.

Detail Description Paragraph - DETX (21):

[0043] In operation, the knob 90 is rotated counterclockwise as illustrated in FIG. 15, causing the gear 92 to move in the same direction. This action causes the reduction drive gear 88 and the rack drive gear 86 to move in a clockwise position, which in turn causes the rack 84 to retract within the housing by a distance of approximately 1 cm per revolution of the knob as indicated at 94. The mechanical advantage is controlled by appropriate sizing of the gears which drive the rack 84. After a sufficient number of rotations, the rack 84 will be fully retracted, as illustrated in FIG. 16 and the outer sheath 10 will be completely removed from the stent 16 so that the catheter 11 can be removed from the patient as described above.

Detail Description Paragraph - DETX (23):

[0045] As shown in FIG. 19, a single rotation of the knob 96 achieves a movement of the power screw 104 of approximately 1 cm, as indicated at 106. The high mechanical advantage provided by the configuration facilitates smooth retraction of the outer sheath 10. After a number of rotations of the knob 96, the power screw 104 will be fully retracted, as illustrated in FIG. 20, and the outer sheath 10 will be completely withdrawn from the stent 16. The catheter 11 can then be removed as described above.

Detail Description Paragraph - DETX (24):

[0046] In summary, each of the disclosed systems provides a significant mechanical advantage which facilitates smooth retraction of the outer sheath 10 which covers the stent 16. This minimizes migration of the stent 10 during sheath retraction, thus ensuring that the stent 16 will remain in its desired

location. In addition, various configurations are provided which are operable in numerous orientations, thus providing convenient and simple use during surgery.

Claims Text - CLTX (2):

1. A stent deployment system for introducing a self-expanding stent into a body vessel, comprising: an inner catheter having a proximal end and a distal end, the distal end being attached to a tip, the inner catheter permitting passage of a guidewire therethrough; a reinforcing spring element surrounding the inner catheter for resisting compression and providing flexibility for moving through a body vessel; an abutment element attached to a distal end of the reinforcing spring element for preventing axial movement of the self-expanding stent in a proximal direction; and an outer catheter having a proximal end and a distal end, the proximal end being attached to a movable member, the distal end surrounding the self-expanding stent, wherein movement of the movable member retracts the outer catheter to release the self-expanding stent.